

We Claim:

1. A pharmaceutical composition, comprising:

- (a) a tiotropium salt (1); and
- (b) a salmeterol salt (2),

optionally in the form of the enantiomers, mixtures of enantiomers, or in the form of the racemates thereof, optionally in the form of the solvates or hydrates and optionally together with a pharmaceutically acceptable excipient.

2. The pharmaceutical composition according to claim 1, wherein the tiotropium salt (1) and the salmeterol salt (2) are contained in a single preparation.

3. The pharmaceutical composition according to claim 1, wherein the tiotropium salt (1) and the salmeterol salt (2) are contained in two separate preparations.

4. The pharmaceutical composition according to claim 1, wherein the tiotropium salt (1) is a chloride, bromide, iodide, methanesulfonate, *para*-toluenesulfonate, or methylsulfate salt.

5. The pharmaceutical composition according to claim 1, wherein the salmeterol salt (2) is a chloride, bromide, sulfate, phosphate, methanesulfonate, acetate, fumarate, succinate, lactate, citrate, xinafoate, or maleate salt, with the proviso that the salmeterol salt (2) is not salmeterol xinafoate if the tiotropium salt (1) is tiotropium bromide.

6. The pharmaceutical composition according to claim 4, wherein the salmeterol salt (2) is a chloride, bromide, sulfate, phosphate, and methanesulfonate salts.

7. The pharmaceutical composition according to claim 1, wherein the relative amount of the tiotropium salt (1) to the salmeterol salt (2) are in a range from 1:300 to 30:1 based upon the ratios by weight of tiotropium (1') to salmeterol (2').

8. The pharmaceutical composition according to claim 1, wherein the relative amount of the tiotropium salt (1) to the salmeterol salt (2) are in a range from 1:230 to 20:1 based upon the ratios by weight of tiotropium (1') to salmeterol (2').
9. The pharmaceutical composition according to claim 1, wherein a single administration corresponds to a dosage of the active substance combination 1' and 2' of from 0.01 µg to 1000 µg.
10. The pharmaceutical composition according to claim 1, wherein a single administration corresponds to a dosage of the active substance combination 1' and 2' of from 0.01 µg to 200 µg.
11. The pharmaceutical composition according to one of claims 1 to 10, wherein the pharmaceutical composition is in a form suitable for inhalation administration.
12. The pharmaceutical composition according to claim 11, wherein the pharmaceutical composition is an inhalable powder.
13. The pharmaceutical composition according to claim 11, wherein the pharmaceutical composition is an inhalable aerosol containing propellant.
14. The pharmaceutical composition according to claim 11, wherein the pharmaceutical composition is an inhalable propellant-free solution.
15. The pharmaceutical composition according to claim 11, wherein the pharmaceutical composition is an inhalable powder, further comprising a suitable physiologically harmless adjuvant selected from monosaccharides, disaccharides, oligo- and polysaccharides, polyalcohols, salts, or mixtures thereof.
16. The inhalable powder according to claim 15, wherein the adjuvant has a maximum mean particle size of up to 250 µm.
17. The inhalable powder according to claim 16, wherein the adjuvant has a maximum mean particle size of between 10 µm and 150 µm.

18. A capsule containing the inhalable powder according to claim 15.
19. A capsule containing the inhalable powder according to claim 16.
20. A capsule containing the inhalable powder according to claim 17.
21. The inhalable powder according to claim 12, consisting essentially of the tiotropium salt (1) and the salmeterol salt (2).
22. The inhalable aerosol containing propellant according to claim 13, wherein the tiotropium salt (1) and the salmeterol salt (2) are in dissolved or dispersed form.
23. The inhalable aerosol containing propellant according to claim 22, wherein the propellant gas is a hydrocarbon or a halohydrocarbons.
24. The inhalable aerosol containing propellant according to claim 23, wherein the propellant gas is *n*-propane, *n*-butane, isobutane, or the chlorinated and/or fluorinated derivatives of methane, ethane, propane, butane, cyclopropane, or cyclobutane.
25. The inhalable aerosol containing propellant according to claim 22, wherein the propellant gas is TG11, TG12, TG134a, TG227, or a mixture thereof.
26. The inhalable aerosol containing propellant according to claim 22, further comprising a cosolvent, stabilizer, surfactant, antioxidant, lubricant, or agent for adjusting the pH.
27. The inhalable aerosol containing propellant according to claim 22, wherein the amount of the tiotropium salt (1) or the salmeterol salt (2) is up to 5% by weight of the pharmaceutical composition based upon the weight of tiotropium (1') or salmeterol (2'), respectively.
28. The inhalable propellant-free solution according to claim 14, further comprising a solvent selected from water, ethanol, or a mixture of water and ethanol.

29. The inhalable propellant-free solution according to claim 28, wherein the pH of the solution is in the range of 2 to 7.

30. The inhalable propellant-free solution according to claim 29, wherein the pH of the solution is in the range of 2 to 5.

31. The inhalable propellant-free solution according to claim 29, wherein the pH is adjusted using an acid selected from hydrochloric acid, hydrobromic acid, nitric acid, sulfuric acid, ascorbic acid, citric acid, malic acid, tartaric acid, maleic acid, succinic acid, fumaric acid, acetic acid, formic acid, and propionic acid, or mixtures thereof.

32. The inhalable propellant-free solution according to claim 28, further comprising an additional cosolvent or adjuvant.

33. The inhalable propellant-free solution according to claim 32, wherein the additional cosolvent has one or more hydroxyl or other polar groups.

34. The inhalable propellant-free solution according to claim 33, wherein the additional cosolvent is an alcohol, glycol, glycerol, polyoxyethylene alcohol, or polyoxyethylene fatty acid ester.

35. The inhalable propellant-free solution according to claim 33, wherein the additional cosolvent is isopropyl alcohol, propylene glycol, polyethylene glycol, polypropylene glycol, glycol ether, glycerol, polyoxyethylene alcohol, or a polyoxyethylene fatty acid ester.

36. The inhalable propellant-free solution according to claim 32, wherein the adjuvant is selected from a surfactant, stabilizer, complexing agent, antioxidant, preservative, flavoring, pharmacologically harmless salt, or vitamin.

37. The inhalable propellant-free solution according to claim 32, wherein the adjuvant is edetic acid or a salt of edetic acid.

38. The inhalable propellant-free solution according to claim 32, wherein the adjuvant is ascorbic acid, vitamin A, vitamin E, or a tocopherols.
39. The inhalable propellant-free solution according to claim 32, wherein the adjuvant is cetylpyridinium chloride, benzalkonium chloride, benzoic acid, or a benzoate.
40. The inhalable propellant-free solution according to claim 14, consisting essentially of: the tiotropium salt (1), the salmeterol salt (2), benzalkonium chloride, sodium edetate, and the solvent.
41. The inhalable propellant-free solution according to claim 14, consisting essentially of: the tiotropium salt (1), the salmeterol salt (2), benzalkonium chloride, and the solvent.
42. The inhalable propellant-free solution according to claim 14, wherein the inhalable propellant-free solution is a concentrate or sterile ready-to-use solution for inhalation.
43. A method of administering the inhalable propellant-free solution according to claim 14 to a patient, comprising nebulizing the inhalable propellant-free solution in an inhaler according to WO 91/14468 or an inhaler as described in Figures 6a and 6b of WO 97/12687.
44. A method of administering the inhalable propellant-free solution according to claim 14 to a patient, comprising nebulizing the inhalable propellant-free solution in an energy-operated free-standing or portable nebulizer which produces inhalable aerosols by means of ultrasound or compressed air according to the Venturi principle or other principles.
45. A method of treating a respiratory disease, the method comprising administering to a patient in need thereof an effective amount of a pharmaceutical composition according to one of claims 1, 4, 5, 6, 7, 8, 9, or 10.

46. The method according to claim 45, wherein the respiratory disease is asthma or COPD.

continued on next page